

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A study on therapeutic and anti-inflammatory effects of *Saccharomyces cerevisiae boulardii* probiotic in asthmatic patients referred to kowsar semnan hospital

Protocol summary

Study aim

A study on therapeutic and anti-inflammatory effects of *Saccharomyces cerevisiae boulardii* probiotic in asthmatic patients referred to kowsar semnan hospital

Design

Clinical trial with parallel control group, double blind, randomized, Control with placebo, single center trial, Sample size 60 people.

Settings and conduct

Semnan Kowsar Hospital. 250 mg of probiotic capsules under the brand name daily yeast for 3 month, 1 to 2 times a day. The participant, the main researcher, health personnel who evaluate the outcomes will not be informed about the grouping of patients and the type of medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Up to 60 years of age; Asthma confirmed by a pulmonologist. Exclusion criteria: Kidney failure; Acute or chronic infection; Cancer.

Intervention groups

Intervention group: In addition to routine asthma treatments; 250 mg of probiotic capsules under the brand name daily yeast for 3 month, 1 to 2 times a day. Before and after the intervention, 7 cc of blood is taken to check for factors such as CRP, peripheral blood eosinophil counts, and IL5. Spirometry is performed before and after intervention for all individuals. Control group: Patients are routinely treated for asthma according to the protocol. Only for comparison with intervention group.

Main outcome variables

Interleukin-5 (IL-5); Eosinophils.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N54**

Registration date: **2020-05-27, 1399/03/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-27, 1399/03/07**

Update count: **0**

Registration date

2020-05-27, 1399/03/07

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-21, 1399/02/02

Expected recruitment end date

2020-10-23, 1399/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study on therapeutic and anti-inflammatory effects of *Saccharomyces cerevisiae boulardii* probiotic in asthmatic patients referred to kowsar semnan hospital

Public title

A study on therapeutic and anti-inflammatory effects of probiotic in asthmatic patients referred to kowsar semnan hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Up to 60 years of age Asthma confirmed by a pulmonologist

Exclusion criteria:

Kidney failure Acute or chronic infection Cancer

Age

To 60 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 2). Using Excel software to generate random number tables

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant, the main researcher, health personnel who evaluate the outcomes will not be informed about the grouping of patients and the type of medication.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2020-04-21, 1399/02/02

Ethics committee reference number

IR.SEMUMS.REC.1399.021

Health conditions studied

1

Description of health condition studied

Asthmatic

ICD-10 code

J45.22

ICD-10 code description

Mild intermittent asthma with status asthmaticus

Primary outcomes

1

Description

Interleukin-5 (IL-5)

Timepoint

Before and after intervention

Method of measurement

ELISA

2

Description

Eosinophils

Timepoint

Before and after intervention

Method of measurement

Cell count by examining peripheral blood smears

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine asthma treatments; 250 mg of probiotic capsules under the brand name daily yeast for 3 month, 1 to 2 times a day. Before and after the intervention, 7 cc of blood is taken to check for factors such as CRP, peripheral blood eosinophil counts, and IL5. Spirometry is performed before and after intervention for all individuals.

Category

Treatment - Drugs

2

Description

Control group: Patients are routinely treated for asthma according to the protocol. Only for comparison with intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Bahador Bagheri

Street address

Street Amin, Semnan

City

Semnan

Province

Semnan

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3519899951

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Ehsani

Street address

Semnan University of Medical Sciences, Basij Blvd,
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fatemehEhsani59@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Bahador Bagheri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Bahador Bagheri

Position

Associate professor

Latest degree

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Associate professor

Latest degree
Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available